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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Victor M. Markowitz

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PROCOPIO, CORY, HARGREAVES & SAVITCH LLP

530 B STREET

SUITE 2100

SAN DIEGO, CA 92101

EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

2168

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/862,424	<b>Applicant(s)</b> MARKOWITZ, VICTOR M.	
	<b>Examiner</b> Cheyne D. Ly	<b>Art Unit</b> 2168	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2005 and 15 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,16-21,24-28,35 and 37-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,16-21,24-28,35 and 37-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' arguments filed November 28, 2005 and May 15, 2006 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The rejection of record has been withdrawn as necessitated by claim amendments.
3. Claims 1, 16-21, 24-28, 35, and 37-41 are examined on the merits.

### **CLAIM REJECTIONS - 35 USC § 103**

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 1, 16-21, 24-28, 35, and 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ermolaeva et al. (1998) (Ermolaeva hereafter) taken with Barillot et al. (1999) (Barillot hereafter).
6. The instant rejection has been necessitated by claim amendments.

### **BASIS FOR REJECTION**

1. Ermolaeva discloses a method for data management and analysis of gene expression data from microarrays. The method of Ermolaeva comprises the ArrayDB system wherein gene

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expression data is stored in a relational database (Abstract etc. and page 20, column 1, Box 1), as in instant claim 1, lines 1-5; claim 21, lines 1-6; and claim 35, lines 1-6.

2. Ermolaeva discloses a complete relational schema of the database is available on request (Figure 2). The authors have provided the PTO a copy of the schema upon the examiner's request. The citation of the Array DB Software Schema is not being used as prior art, but only to expand on the inherent characteristics of said relational database. Further, the limitation of "separate databases" has not been specifically defined in the instant specification. Therefore, the relational database of Ermolaeva comprising separate tables (databases) is consistent with the required limitation. For example, the adb\_CALC\_INTENSITY\_99 relational table contains sample data (sample database), UniGene and NonUniGene relational tables contain gene annotation data (annotation database). "The relational database underlying the ArrayDB system stores extensive information pertaining to each clone in the microarray, including a brief gene description, GenBank accession number, IMAGE clone identifier" (page 20, column 2, lines 17-35). Further, "[t]he 'clone' field contains IMAGE clone identifier and is hyperlinked to the dbEST records containing the sequences of this clone" (page 21, Figure 3), as in instant claim 1, lines 6-7 and 20-23; claim 21, lines 7-9 and 22-25; and claim 35, lines 1-8.

3. Clone information stored in the ArrayDB is extracted from UniGene (for example, sequence definition and accession number) (known standardized identifier). However, the design accommodates addition of newly isolated clones for which accession numbers or meaningful names are not yet available (unknown standardized identifier). ArrayDB

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automatically scans a directory for new intensity data (expression level) (page 20, column 2, last paragraph). The disclosure of newly isolated clones has been reasonably construed as sample data directed to genomics. The gene fragment classification cited above is consistent with the disclosure for said classification in the instant specification (page 8, last paragraph). Further, the gene fragments are grouped in to “only up-regulated clones or only down-regulated clones” (Figure 4), which represents “at least two gene fragment classes” based on expression results, as in instant claim 1, lines 8-19, claim 21, lines 10-21; and claim 35, lines 9-20.

4. The Web-based user interface to the ArrayDB system supports database queries which allows retrieval of distinct types of information ranging from clone data to intensity data to analysis results. “ArrayDB supports database queries by different fields, such as clone ID, title, experiment number, sequence accession number...” ArrayDB provides hyperlinks to other databases such as dbEST, GenBank, UniGene, or KEGG (page 21, column 1, lines 5-16). The queries generates results comprising expression data corresponding to the clones and intensity data which are displayed in the Multiexperiment viewer window (Figure 4), as in instant claim 1, lines 24-27; claim 21, lines 26-30; and claim 35, lines 20-25.

#### MOTIVATION TO COMBINE

5. However, Ermolaeva does not describe the limitation of “**communicating between the separate databases, a user interface and a runtime engine using a CORBA interface.**”

Barillot describes CORBA as being urgently need by the scientific community to help standardize the exchange of biological data by providing a common protocol and the

definition of shared data structures (Abstract etc.). While, Ermolaeva describes ArrayDB for the integration of biological data (Abstract etc.). One of ordinary skill in the art at the time of the invention would have been motivated by Barillot to use CORBA to standardize the exchange of biological data in ArrayDB described by Ermolaeva. Therefore, it would have been obvious to one of ordinary skill in the art to use ArrayDB as described by Ermolaeva with the CORBA technology, as described by Barillot, to to standardize the exchange of biological data.

6. Ermolaeva discloses the ranking number is overlaid on the image for clones that have satisfied the query criteria wherein the ranking is according to ratio value. The ArrayViewer generates a cluster report (gene set). The MultipExperiment view supports analysis data from multiple experiments (across sample sets) (page 21, column 2, Data Analysis §, and Figure 3), as in instant claims 16, 24, and 37. Therefore, it would have been obvious to one of ordinary skill in the art to use ArrayDB as described by Ermolaeva with the CORBA technology, as described by Barillot, to to standardize the exchange of biological data.

7. Ermolaeva discloses the ArrayViewer comprises textboxes for specifying call value thresholds based on two fluorescent probes (pair) for identifying gene sets being present and absent within the sample set as indicated by the “boxes” and ranking gene signature by ascending ratio value (pages 21-22, Data Analysis §, and Figure 3), as in instant claims 17, 25, and 38. Therefore, it would have been obvious to one of ordinary skill in the art to use

ArrayDB as described by Ermolaeva with the CORBA technology, as described by Barillot, to to standardize the exchange of biological data.

8. Ermolaeva discloses the ArrayDB via the MultipExperiment (workspace manager) provides the comparison of data over multiple experiments by comparing multiple samples of a particular type of tumour or over a time course to determine differential expression. For example, the reference (control) sample is cDNA prepared from yeast cells harvest at the first interval after inoculation (page 23, column 1, lines 3-18). The control sample represents the first sample set and the time course sample represents the second sample, as in instant claims 18, 19, 26, 27, and 39, and 40. Therefore, it would have been obvious to one of ordinary skill in the art to use ArrayDB as described by Ermolaeva with the CORBA technology, as described by Barillot, to to standardize the exchange of biological data.

9. Ermolaeva discloses ArrayDB via the ArrayViewer allows users to select a range of expression ratios wherein ArrayViewer returns information on genes with expression ratios in said range. Further, the MultipExperiment returns clones with high or low ratios in an experimental series (page 22, column 1, lines 15-18, and column 2, first paragraph), as in instant claims 20, 28, and 41. Therefore, it would have been obvious to one of ordinary skill in the art to use ArrayDB as described by Ermolaeva with the CORBA technology, as described by Barillot, to to standardize the exchange of biological data.

## RESPONSE TO ARGUMENTS

10. On pages 9-10, Applicant cites Exhibits A and B to argue that the relational database of Ermolaeva is not the same as multiple, distinct databases within the database management systems of Applicant.” Applicant’s argument via Exhibits A and B have been fully considered, however, they are not persuasive because Exhibit A and B support that the relational database of Ermolaeva comprises “separate databases” as required by the instant specification. It is noted that the limitation of “separate databases” is recited in the claims, which is different from the argued limitation of multiple, distinct databases.

11. Specific to the limitation of “separate databases”, Exhibit B describes “A relational database is a big spreadsheet...Each table in the database is one spreadsheet.” Exhibit B exemplifies the database as comprising a single mailing\_list table. The simplest database supported by Exhibit B is a database where there is a single table. Using the analogy applied by Applicant via Exhibit B, Ermolaeva describes multiples tables in the relational database within the ArrayDB system, which is supported by Exhibits A and B to be “separate databases.”

12. It is re-iterated that Ramakrishnan R. describes “A database is a collection of data, typically describing the activities of one or more related organizations” (page 1). The American Heritage College Dictionary (provided with the instant Office Action) defines a database as “A collection of data arranged for ease of retrieval” (page 361). Further, Date C. J. (provided with the instant Office Action) describes a database comprising a single table (page 3, especially Figure 1.1). The Array DB Software Schema discloses the relational database comprising a plurality of separate tables, which have been reasonably construed as



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“[a] collection of data”; therefore, represents the required “separate databases” as defined by Exhibit A, Ramakrishnan R., Date C. J., and The American Heritage College Dictionary.

The ArrayDB Software Schema of Ermolaeva reasonably represents the “separate databases” exemplified in Figure 7 of the instant specification.

13. Specific to the amended limitation of “**communication between the separate databases...using a CORBA interface**”, it has been noted above that Ermolaeva does not describe the new limitation. However, the deficiency Ermolaeva has been address by the citation Barillot et al., as necessitated by claim amendments. Barillot describes CORBA as being urgently need by the scientific community to help standardize the exchange of biological data by providing a common protocol and the definition of shared data structures (Abstract etc.). While, Ermolaeva describes ArrayDB for the integration of biological data (Abstract etc.). One of ordinary skill in the art at the time of the invention would have been motivated by Barillot to use CORBA to standardize the exchange of biological data in ArrayDB described by Ermolaeva. Therefore, it would have been obvious to one of ordinary skill in the art to use ArrayDB as described by Ermolaeva with the CORBA technology, as described by Barillot, to to standardize the exchange of biological data.

### CONCLUSION

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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17. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The USPTO's official fax number is 571-272-8300.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Vo, can be reached on (571) 272-3642.

C. Dune Ly / *cr*  
Patent Examiner  
8/2/06

A handwritten signature in black ink, appearing to read 'Tim Vo', with a stylized, flowing script.

TIM VO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 2100